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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/028,172	12/21/2001	Yoichi Takahama	322732000401	2837

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EXAMINER	
LI, BAO Q	

ART UNIT	PAPER NUMBER
1648	

DATE MAILED: 11/03/2003

11

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/028,172	TAKAHAMA ET AL.	
	Examiner	Art Unit	
	Bao Qun Li	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *28 August 2003* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *13-30* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *13-30* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☒ Certified copies of the priority documents have been received in Application No. *08/850,328* .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *3&7* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Amendment , paper No. 5 has been acknowledged. Claims 1-12 are canceled. New claims 13-30 have been added. Claims 13-30 are pending.

Election/Restrictions

1. Applicant's election with traverse of Group II, claims 13-15, 17-19 and 21-30 in Paper No. 10 is acknowledged. The traversal is on the ground(s) that claim 13 is amended. Claim 13 now refers to one or more synthesized HCV antigens and therefore, Office should not restrict a single claim 13.

2. Upon considering Applicants' amendment, Claim 16 is rejoined with elected group. Therefore, claims 13-30 are considered before the examiner.

Priority

3. This application filed under former 37 CFR 1.60 lacks the necessary reference to the prior application. A statement reading "This is a continuation of Application No. 08/850,328, filed May 02, 1997." should be entered following the title of the invention or as the first sentence of the specification. Also, the current status of all nonprovisional parent applications referenced should be included.

Double Patenting

4. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground

provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

5. Claims 13-30 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 2, 4-6 and 7 of U.S. Patent No. 6,379,886B1. Although the conflicting claims are not identical, they are not patentably distinct from each other because the scopes of conflict claims are overlapping.

6. Claims 1, 2, 4-6 and 7 of Patent "886B1" are directed to a diagnostic reagent comprising a solid phase bound with (1) three or more different HCV antigen-carrier protein conjugates selected from group consisting of HCV core, NS3, NS4 and NS5 antigens or (2) three more different HCV antigen components selected from HCV core, NS3, NS4 and NS5 antigen, wherein only antigen selected from group consisting of core antigen, NS4 antigen and NS5 antigen is attached to the carrier protein in this situation. The carrier protein is a water soluble protein selected from group consisting of BSA, ovalbumin or hemocyani that binds to at least one of the antigen components selected from group consisting of core, NS3, NS4 and NS5 antigen. The ratio of a carrier protein to an antigenic protein is about 1:3 to 1:20. The solid phase is a carrier particle.

7. The claims 13-30 of current application are directed to a diagnostic reagent of a solid phase particle made by sensitizing a solid phase with a genetic recombinant HCV antigen of NS3 and one of more other synthetic structural and non-structural HCV antigens including core, NS4 and NS5 peptide antigen, wherein either synthetic antigens or recombinant antigen can be conjugated with a hydrophobic protein selected from the group consisting of BSV, ovalbumin and hemocyani in the ration of 1:3 to 1:20.

8. While the claimed invention cited by claims 13-30 words differently from the claims 1, 2, 4-6 and 7 of Patent "886B1", the Patent "886B1" discloses same materials and methods, especially the same HCV core, NS3 NS4 and NS5 protein antigens having same structural characteristics to make a diagnostic reagent for detecting HCV antibodies (See examples 109 from col. 4 to col. 10). Moreover, the claimed product of claims 1-2, and 4-7 in Patent "886B1"

also have all limitations of claims 13-30, such as attached to same carrier protein and bound to a same solid phase. While claims 1-2, and 4-7 of Patent "886B1" describe the HCV antigen as an antigen in general, whereas the claims of current application describe the HCV antigens as a recombinant antigen and synthetic antigens. However, the generic claims of the HCV antigens in the patent "886B1" would include all antigenic proteins of HCV in any forms whether they are recombinant or synthetic as well as naturally isolated ones.

9. Therefore, it would have been for a person with ordinary skill in the art to be motivated to make the same diagnostic reagent by using same HCV antigens in either recombinant or synthetic forms, and further conjugating them with the same carrier protein and coating them onto the same solid phase to form an immunogenic carrier particle sensitized by HCV antigens, absence of unexpected result.

10. This is an obvious type, nonstatutory double patenting rejection, a timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection.

Claim Rejections - 35 USC § 102

11. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

12. Claims 13, 14, 15, 16, 17 and 24 are rejected under 35 U.S.C. 102(e) as being anticipated by Houghton et al. (US Patent No. 5,683,864A).

13. Houghton et al. teach that a combination of hepatitis C (HCV) antigens comprising the first HCV antigen of HCV C domain (corresponding to amino acid (aa) residues 1-120 of core region) and other two additional HCV antigens selected from HCV NS3, NS4 and NS5 antigen (See Fig. 2) are coated onto microplates used for detecting the presence of HCV antibodies in serum or control samples. The said antigens are either produced recombinant or chemical synthesized antigens, which are in the form individually bound to a common solid matrix selected from a plate well, a head and dipstick (See claims 1-3, 5-7, 9-10, 12-15, 17, 18 and 19-22, lines 29-33 on col. 1 and 19-20 on col. 2 and lines 57 on col. to line 27 on 20). Therefore, the claimed invention is anticipated by the cited reference.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bao Qun Li whose telephone number is 703-305-1695. The examiner can normally be reached on 7:00 to 4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on 703-308-4027. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Bao Qun Li

October 21, 2003

Baoqun Li